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Canadian Patent Office

Certification

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Specification and Drawings, as originally filed, with Application for Patent Serial No: **2,201,819**, on April 4, 1997, by **INSTITUT NO INC.**, assignee of Gilbert Blaise and Luc Dubé, for "Injection System for Delivery of a Gaseous Substance".

S. Gagné
Agent certificateur/Certifying Officer

April 16, 1998
Date

ABSTRACT OF THE DISCLOSURE

A injection system for the delivery of a gaseous substance to a patient respiratory system is described herein. The injection system includes a controller unit and a valve assembly including a valve and a valve actuator allowing partial opening of the valve and controlled by the controller unit. The controller unit is supplied with gas flow data and controls the valve assembly so that the opening of the valve is a function to the gas flow to thereby enable the control over the concentration of the gaseous substance delivered to the patient.

TITLE OF THE INVENTION

INJECTION SYSTEM FOR DELIVERY OF A GASEOUS SUBSTANCE

FIELD OF THE INVENTION

The present invention relates to an injection system for delivery of a gaseous substance. More specifically, the present invention relates to an injection system for delivery of a gaseous substance to a patient, where the concentration of the gaseous substance delivered to the patient is essentially constant during the patient inspiratory phase.

BACKGROUND OF THE INVENTION

It has been found that various chemical compounds, such as, for example, nitric oxide (NO), administered during a patient inspiratory phase may provide beneficial effects.

For example, NO presents some lung vasodilator properties that may be helpful for respiratory distress conditions such as respiratory distress syndrome of newborn.

Apparatus for delivering such gaseous chemical compounds have therefore been designed to deliver the compounds during the patient's inspiratory phase.

One such apparatus is described in Canadian Patent Application N° 2,106,696, filed on September 22, 1993 and published on

March 25, 1994 and naming Robert Briand and Marie-Hélène Renaudin as inventors. In this document, Briand et al. describe an apparatus for delivering controlled doses of NO to the respiratory system of the patient without conventional pre-mixing of the NO with oxygen supplied by a ventilator device. The apparatus therefore includes means for detecting the beginning of a patient inspiratory phase and to open an electromagnetic valve for a predetermined duration to supply a controlled dose of NO. The duration and the pressure of the NO supplied dose is adjusted so as to obtain the desired NO concentration with respect to the average inhalation volume of the patient. The NO dose supplied is therefore not directly related to the inhalation volume of the patient. Of course, there is no NO injection during the expiration phase.

A major drawback of the apparatus described by Briand et al. is the automatic opening of the electromagnetic valve for a predetermined duration each time the beginning of an inhalation phase is detected. Indeed, if the patient repetitively draws short breaths, harm may be caused by the high concentration of NO.

In an article entitled: "Comparison of two administration techniques on inhaled nitric oxide on nitrogen dioxide production", published in Canadian journal of Anaesthesiology 1995, Vol. 42:10, pages 922-927, Dubé et al. describe an injection system for delivering NO during inspiratory phase. In this injection system, an electronic circuit detects the beginning and the end of each inspiration by processing a flow signal supplied by a ventilator. At the beginning of the inspiratory phase, the electronic circuit opens a solenoid valve and NO is injected into the respiratory line. At the end of the inspiratory phase, the electronic circuit closes the solenoid valve and the injection of NO is stopped.

Figure 1 of the appended drawings is a graph of the inspiratory gas flow 20 vs time for a conventional ventilator when the ventilator is in a first mode. When it is in this mode, the flow of inspiratory gas is constantly delivered for a predetermined duration (inspiratory phase 22) and the patient then expires (expiratory phase 24). In the injection system proposed by Dubé et al., when the gas flow reaches a predetermined threshold level 26, a solenoid valve is open, delivering NO to the patient. The line 28 illustrates the injected flow of NO in the inspiration circuit over time. It is to be noted that the scale is different for the flow of inspiratory gas 20 and the flow 28 of NO. Indeed, line 28 illustrating the flow of NO is shown scaled up for illustrative purposes.

Since the solenoid valve used by Dubé et al. is of the type fully open/fully closed, the flow 28 of NO is constant when the valve is open. As can be seen from Figure 2, the concentration 29 of NO is essentially constant over time during the inspiratory phases. When the inspiratory gas flow falls below the threshold level 26, the solenoid valve is closed, stopping the flow of NO.

Figure 3 is a graph of the gas flow 30 vs time for a conventional ventilator when the ventilator is in a second ventilating mode. When it is in this mode, the flow of gas is not constantly delivered for a predetermined duration but follows a particular curve during the inspiratory phase 32 and the patient then expires (expiratory phase 34). In the injection system proposed by Dubé et al., when the gas flow reaches a predetermined threshold level 36, the solenoid valve is open delivering NO to the patient. The line 38 illustrates the flow of NO over time. Again, it is to be noted that the scale is different for the flow of

inspiratory gas and the flow 38 of NO. Indeed, line 38 illustrating the flow of NO is shown scaled up for illustrative purposes.

Since the solenoid valve used by Dubé et al. is of the type fully open/fully closed, the flow of NO is constant when the valve is open. As can be seen from Figure 4, the concentration of NO (line 39) is not constant over time during the inspiratory phases but varies inversely with the flow of gas since the flow of NO is constant. When the gas flow falls below the threshold level 36, the solenoid valve is closed.

A drawback of the injection system of Dubé et al. is that, in certain cases, the NO concentration is not constant during the inspiratory phase.

OBJECTS OF THE INVENTION

An object of the present invention is therefore to provide an improved apparatus for pulsed delivery of gaseous substances.

Another object of the invention is to provide an apparatus for delivery of gaseous substances delivering an essentially constant concentration of the gaseous substance during the inspiratory phase.

SUMMARY OF THE INVENTION

More specifically, in accordance with the present invention, there is provided an injection system for the delivery of a

gaseous substance from a container to a patient through a conduit coupled to the patient respiratory system; the injection system comprising:

a controller unit for controlling the injection system;

a valve assembly in connection with the conduit to selectively allow the delivery of the gaseous substance from the container to the conduit; the valve assembly including a valve and valve actuating means allowing variable opening of the valve; the valve actuating means being coupled to the controller means to be controlled thereby;

a flowmeter for quantitatively measuring inspiratory gas flow in the conduit; the flowmeter being coupled to the controller unit to supply inspiratory gas flow data thereto;

the controller unit controlling the valve assembly so that the variable opening of the valve is responsive to the inspiratory gas flow in the conduit.

According to another aspect of the present invention, there is provided an injection system for the delivery of a gaseous substance from a container to a patient through a conduit coupled to the patient respiratory system; the respiratory system of the patient being also coupled to a ventilator forcing inspiratory gas therein; the injection system comprising:

a controller unit for controlling the injection system; the controller unit receiving inspiratory gas flow data from the ventilator;

a valve assembly in connection with the conduit to selectively allow the delivery of the gaseous substance from the container to the conduit; the valve assembly including a valve and valve actuating means allowing variable opening of the valve; the valve actuating means being coupled to the controller means to be controlled thereby;

the controller unit controlling the valve assembly so that the variable opening of the valve is responsive to the inspiratory gas flow supplied to the patient.

A major advantage of the present invention concerns the variable opening of the valve to increase or decrease the quantity of the gaseous substance delivered to the patient. Hence, it is possible to control the opening of the valve so that the variable opening of the valve is responsive to the inspiratory gas flow directed towards the respiratory system of the patient and thereby controlling the concentration of the gaseous substance delivered to the patient.

Other objects, advantages and features of the present invention will become more apparent upon reading of the following non restrictive description of preferred embodiments thereof, given by way of example only with reference to the accompanying drawings.

The subject of the present invention was developed at *"Le Département de physique biomédicale, Pavillon Notre-Dame, Centre hospitalier de l'Université de Montréal (CHUM)"*

BRIEF DESCRIPTION OF THE DRAWINGS

In the appended drawings:

Figure 1, which is labelled "PRIOR ART", illustrates a graph of flow vs time for a conventional ventilator when the ventilator is in a first mode;

Figure 2 , which is labelled "PRIOR ART", illustrates a graph of nitric oxide concentration vs time corresponding to the graph of Figure 1;

Figure 3, which is labelled "PRIOR ART", illustrates a graph of flow vs time for a conventional ventilator when the ventilator is in a second mode;

Figure 4 , which is labelled "PRIOR ART", illustrates a graph of nitric oxide concentration vs time corresponding to the graph of Figure 3;

Figure 5 schematically illustrates an injection system according to an embodiment of the present invention, the injection system being installed to a conventional ventilator;

Figure 6 schematically illustrates the injection system of Figure 5 when the injection system is not connected to a ventilator;

Figure 7, illustrates a graph of flow vs time for a injection system according to the present invention, the inspiratory phase illustrated being a large spontaneous inspiration;

Figure 8 illustrates a graph of nitric oxide concentration vs time corresponding to the graph of Figure 7;

Figure 9, illustrates a graph of flow vs time for a injection system according to the present invention, the inspiratory phase illustrated being a small spontaneous inspiration;

Figure 10 illustrates a graph of nitric oxide concentration vs time corresponding to the graph of Figure 9;

Figure 11 illustrates a graph of flow vs time for a injection system according to the present invention, the inspiratory phase illustrated being a large spontaneous inspiration;

Figure 12 illustrates a graph of nitric oxide concentration vs time corresponding to the graph of Figure 11;

Figure 13, illustrates a graph of flow vs time for a injection system according to the present invention, the inspiratory phase illustrated being a large spontaneous inspiration;

Figure 14 illustrates a graph of nitric oxide concentration vs time corresponding to the graph of Figure 13;

Figure 15 is a block diagram showing the simplified operation of the injection system of Figure 5; and

Figure 16 is a block diagram showing the operation of the injection system of Figure 5, including safety features.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 5 of the appended drawings illustrates an injection system 100 according to an embodiment of the present invention. The injection system 100 includes a controller unit 102, a valve assembly 104 and a flowmeter 106.

The injection system 100 is illustrated in Figure 5 as being connected to a conventional ventilator 108 through a data cable 110, to a source of a gaseous substance 112 through a conduit 114 and to a patient 116 through an inspiratory conduit 118.

It is to be noted that the following description of the injection system 100 will be given with the particular example of nitric oxide (NO) injection, but that the system 100 could be used to inject other gaseous substance in the respiratory system of a patient.

The source of gaseous substance (NO) 112 includes a NO container 120, a pressure reducer 122 connected to the container 120 and a precision flowmeter 124 adjusting the maximum flow rate of NO in the injection system 100 and connected to the pressure reducer 122. The conduit 114 pneumatically connects the precision flowmeter 124 to a fluid input 126 of the valve assembly 104.

The ventilator 108, when in operation, repetitively supplies a predetermined quantity of inspiratory gas to the respiratory system of the patient 116 through the inspiratory conduit 118 connected to an endotracheal tube 128.

The inspiratory gas supplied to the patient goes through the flowmeter 106, via conduit 130, thereby enabling the flowmeter 106 to measure the inspiratory gas flow supplied to the patient 116. Inspiratory gas flow data is supplied to the controller unit 102 via a data cable 132, interconnecting an inspiratory gas flow data output 134 of the flowmeter 106 and an inspiratory gas flow data input 136 of the controller

unit 102. Of course, the inspiratory gas flow data is either in analog or digital format, compatible with the controller unit 102.

The data cable 132 is illustrated in dashed line in Figure 5 since the data cable 132, along with the flowmeter 106, are not essential to the operation of the injection system 100 when the injection system is connected to a conventional ventilator 108 provided with a flow data output. Indeed, the ventilator 108 includes an inspiratory gas flow data output 138 electrically connected to an inspiratory gas flow data input 140 of the controller unit 102 through the data cable 110. The controller unit 108 is therefore supplied with inspiratory gas flow data from either the independent flowmeter 106 or the data flow output 138 of the ventilator 108.

The controller unit 102 includes a control output 142 electrically connected to a control input 144 of the valve assembly 104 via a control cable 146. The control unit 102 therefore controls the variable opening of the valve assembly 104. The valve assembly 104 may be a normally closed valve assembly or a normally open valve assembly.

The valve assembly 104 also includes a fluid output 148 pneumatically connected to conduit 118 through a conduit 150 and a "Y" junction 152.

As can be seen from Figure 5, the ventilator 108 also includes an expiratory gas inlet 154 connected to the conduit 118 through a conduit 156 and a "Y" junction 158. The patient's expiration gases is therefore returned to the ventilator 108.

In operation, when the controller 102 determines, with the inspiratory gas flow data supplied by either the flowmeter 106 or the ventilator 108, that the patient enters an inspiratory phase, it generates a control signal, supplied to the valve assembly 104 via the control cable 146, to cause the opening of the valve assembly 104 that will allow NO to be transferred from the container 120 to the respiratory system of the patient's through the conduits 114, 150, 118 and endotracheal tube 128. The opening of the valve assembly 104 is variable and is a function of the inspiratory gas flow data supplied to the controller unit 102. Therefore, the concentration of NO injected to the patient during the inspiratory phase is essentially constant since the opening of the valve assembly 104 is proportional to the inspiratory gas flow detected. As will be described hereinafter with reference to Figures 11-14, the concentration of injected NO could be non linear with respect to time.

It is to be noted that the valve assembly 104 generally includes a valve portion 160 including the fluid input 126 and output 148 and a valve actuating portion 162 including the control input 144. The actuating portion advantageously transduces an electric signal supplied to the control input 144 to a mechanical opening of the valve portion 160.

Turning now to Figure 15, of the appended drawings, a simplified block diagram 200 of the operation of the injection system will be described. When the system is started (step 202) it is initialized (step 203). A sample of the inspiratory gas flow (IGF) is then taken (step 204), and is converted to a digital value (step 206) before being supplied to a comparator (step 208). The threshold level (REF, step 210 and numeral 26 in Figure 5) is also converted to a digital value (step 212) before being supplied to the comparator of step 208.

The comparator then compares IGF and REF to determine if the inspiratory gas flow is greater than the threshold. If so, the valve assembly 104 is activated (step 214) and the opening of the valve 160 by the valve actuation 162 is a function of the inspiratory gas flow level (IGF). If not, the valve 160 is deactivated. Of course, as will be described hereinafter, the opening of the valve 160 may be non linear.

Figure 6 of the appended drawings illustrates the injection system 100 used without a ventilator. The only major difference in the operation of the injection system 100 when used without a ventilator is that the inspiratory gas flow data is supplied to the controller unit by the flowmeter 106.

This is a major advantage to be able to use the injection system 100 without a ventilator since the injection of NO may be continued even though the patient 116 does not require a ventilator. The use of the injection system 100 without a ventilator is possible, without danger to the patient, because of the proportional opening of the valve according to the inspiratory gas flow level. Indeed, even if the patient draws short breaths, the concentration of NO with be essentially constant during the inspiratory phases.

Figure 7 of the appended drawings is a graph schematically illustrating the flow 300 vs time for unassisted respiration by a patient. During the inspiratory phase 302 the inspiratory gas flow rise and falls to form a semi-sinusoidal curve. The patient then expires (see expiratory phase 304). When the injection system 100, as illustrated in Figure 6, is used to inject NO to the patient during the inspiratory phase 302, the flow 306 of NO will begin when the inspiratory gas flow reaches

a predetermined threshold 308. The rate of NO injection will then follow the inspiratory gas flow. When the inspiratory gas flow falls below the threshold level 308, the flow of NO is stopped. It is to be noted that the scale is different for the inspiratory gas flow and the flow 306 of NO. Indeed, line 306 illustrating the flow of NO is shown scaled up for illustrative purposes.

As can be seen from Figure 8, that schematically illustrates the NO concentration 310 vs time, the concentration of NO is constant during the patient's inspiratory phase.

Figures 9 and 10 are respectively similar to Figures 7 and 8 but illustrate a patient taking a relatively small inspiration. As can be seen from Figure 10, a resulting NO concentration 310' is essentially equal to the NO concentration 310 of Figure 8. Indeed, with the proportional opening of the valve injecting the NO, changes in the inspiratory gas flow does not modify the injected NO concentration.

As will be readily apparent to one skilled in the art, the inspiratory gas supplied to the patient during the beginning of the inspiratory phase will reach the alveola of the patient, and the inspiratory gas supplied to the patient during the end of the inspiratory phase will stay in the trachea and bronchial tree.

Figures 11 and 12 illustrate the operation of the injection system of Figures 5 or 6 when the opening of the valve assembly 104 is not linear but varies in time to deliver a higher concentration 406 of NO during the beginning of the inspiratory phase 402 and to decrease the

concentration of NO (see line 408) after a predetermined and programmable time period 410.

The NO flow pattern illustrated in Figure 12 could be beneficial to a patient who requires a larger concentration of NO in his alveola than in his bronchial tree.

Similarly, Figures 13 and 14 illustrate the operation of the injection system of Figures 5 or 6 when the opening of the valve assembly 104 is not linear but varies in time to deliver a lower concentration 406' of NO during the beginning of the inspiratory phase 402' and to increase the concentration of NO (see line 408') after a predetermined and programmable time period 410'.

The NO flow pattern illustrated in Figure 14 could be beneficial to a patient who requires a larger concentration of NO in his bronchial tree than in his alveola.

One skilled in the art will easily be able to modify the configuration of the control unit 102 to achieve the NO concentrations of Figures 12 or 14, or of any other suitable NO concentration.

Figure 16 is a block diagram illustrating an other mode of operation of the injection system 100. It is to be noted that the mode of operation of Figure 16 could be used when the injection system 100 is used in conjunction with a ventilator 108 (see Figure 5). However, this mode of operation is advantageously used when the injection system 100 is used without a ventilator as can be seen in Figure 6.

The mode of operation of Figure 16 is similar to the mode of operation of Figure 15. The extra steps, described hereinafter, are taken to provide safe operation of the injection system 100.

In step 216', a first variable (T_{inj}), representing the duration of an injection, is reset and a second variable ($T_{bet\ inj}$), representing the duration between injection, in incremented. Then, in step 218, the second variable $T_{bet\ inj}$ is compared to a predetermined reference number (Y, steps 220 and 222) to activate an alarm and stop the injection system (step 224) should $T_{bet\ inj}$ be greater than Y. This alarm would indicate that there is a condition preventing the normal injection of NO and that supervision is required.

Similarly, in step 214', T_{inj} is incremented and $T_{bet\ inj}$ is reset. Then, in step 226, the second variable T_{inj} is compared to a predetermined reference number (X, steps 228 and 230) to activate an alarm and stop the injection system (step 232) should T_{inj} be greater than X. This alarm would indicate that a malfunction exists in the injection system and that the valve is continuously open.

Of course, the analog to digital conversion steps 206, 212, 222 and 230 could be omitted if the data is already in a digital format.

As will be apparent to one of ordinary skill in the art, the variable opening of the valve assembly 104 is not essentially proportional to the inspiratory gas flow supplied to the patient. Indeed, the opening could be responsive to the inspiratory gas flow in any other suitable manner.

It is to be noted that the concentration of NO and of NO_2 (or of any other gaseous substance injected and their derivative) could be monitored downstream from the T junction 152 by using an appropriate monitoring system for the gaseous substance injected.

It is also to be noted that any adequate flowmeter may be used for the flowmeter 106.

As will be readily apparent to one skilled in the art, the controller unit 102 could include an electronic circuit, a programmable micro controller and/or a microprocessor, to control the operation of the injection system 100.

Although the present invention has been described hereinabove by way of preferred embodiments thereof, it can be modified, without departing from the spirit and nature of the subject invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. An injection system for the delivery of a gaseous substance from a container to a a patient through a conduit coupled to the patient respiratory system; said injection system comprising:

a controller unit for controlling said injection system;

a valve assembly in connection with the conduit to selectively allow the delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said controller means to be controlled thereby;

a flowmeter for quantitatively measuring inspiratory gas flow in the conduit; said flowmeter being coupled to said controller unit to supply inspiratory gas flow data thereto;

said controller unit controlling said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow in the conduit.

2. An injection system as recited in claim 1, wherein said variable opening of said valve is proportionally responsive to said inspiratory gas flow in the conduit.

3. An injection system as recited in claim 1, wherein said controller unit opens said valve in response to said inspiratory gas flow when said inspiratory gas flow exceeds a predetermined threshold level; said injection system therefore delivering the gaseous substance only when the patient is in an inspiratory phase.

4. An injection system as recited in claim 3, wherein said controller unit includes an alarm actuated when a duration between two consecutive inspiratory phases exceeds a predetermined duration limit.

5. An injection system as recited in claim 3, wherein said controller unit includes an alarm actuated when a duration of an inspiratory phase exceeds a predetermined duration limit.

6. An injection system as recited in claims 4 or 5, wherein said injection system is deactivated when said alarm is actuated.

7. An injection system as recited in claims 1, 2, 3, 4, 5 or 6, wherein said gaseous substance includes nitric oxide.

8. An injection system for the delivery of a gaseous substance from a container to a patient through a conduit coupled to the patient respiratory system; the respiratory system of the patient being also coupled to a ventilator forcing inspiratory gas therein; said injection system comprising:

a controller unit for controlling said injection system; said controller unit receiving inspiratory gas flow data from the ventilator;

a valve assembly in connection with the conduit to selectively allow the delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said controller means to be controlled thereby;

said controller unit controlling said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow supplied to the patient.

9. An injection system as recited in claim 8, wherein said variable opening of said valve is proportionally responsive to said inspiratory gas flow forced by the ventilator in the respiratory system of the patient.

10. An injection system as recited in claim 8, wherein said controller unit opens said valve in response to said inspiratory gas flow when said inspiratory gas flow exceeds a predetermined threshold level; said injection system therefore delivering the gaseous substance only when the patient is in an inspiratory phase.

11. An injection system as recited in claim 10, wherein said controller unit includes an alarm actuated when a duration between two consecutive inspiratory phases exceeds a predetermined duration limit.

12. An injection system as recited in claim 10, wherein said controller unit includes an alarm actuated when a duration of an inspiratory phase exceeds a predetermined duration limit.

13. An injection system as recited in claims 11 or 12, wherein said injection system is deactivated when said alarm is actuated.

14. An injection system as recited in claims 8, 9, 10, 11, 12 or 13, wherein said gaseous substance includes nitric oxide.

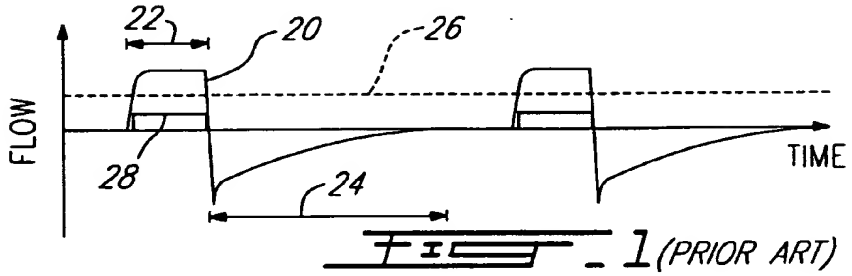

Fig. 1 (PRIOR ART)

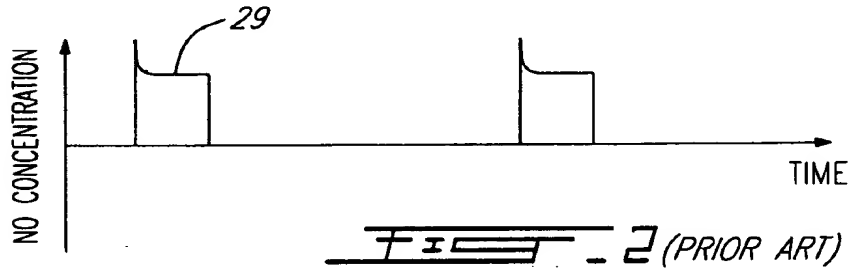

Fig. 2 (PRIOR ART)

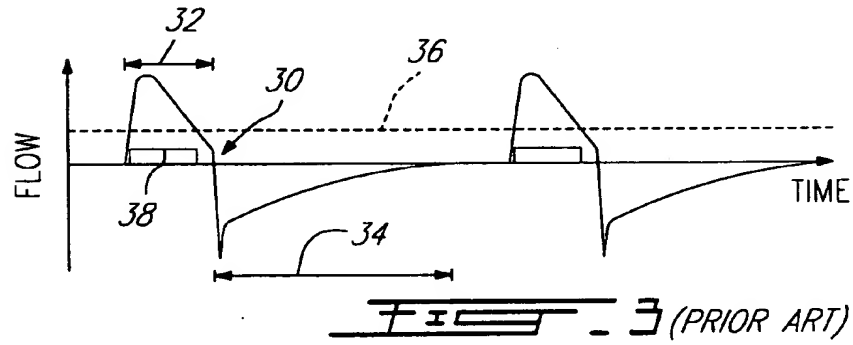

Fig. 3 (PRIOR ART)

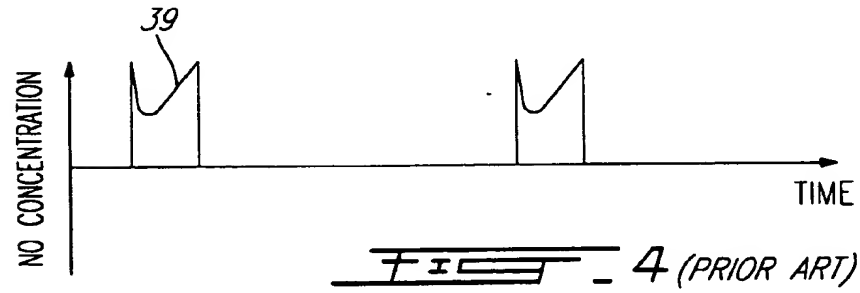

Fig. 4 (PRIOR ART)

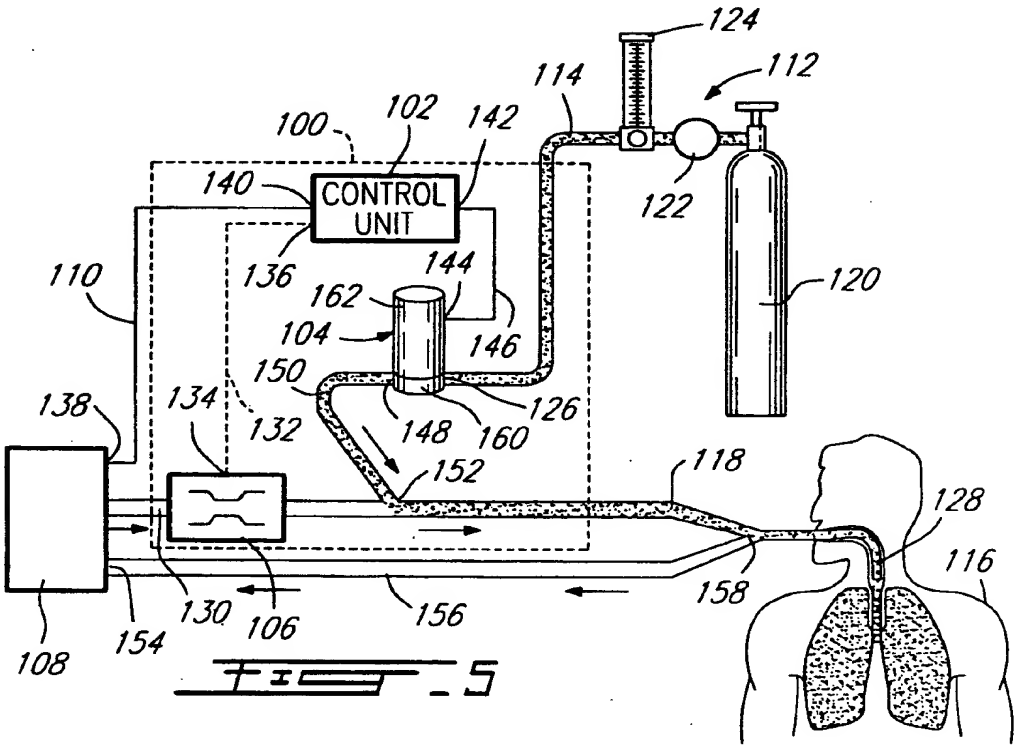
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Fig. 5

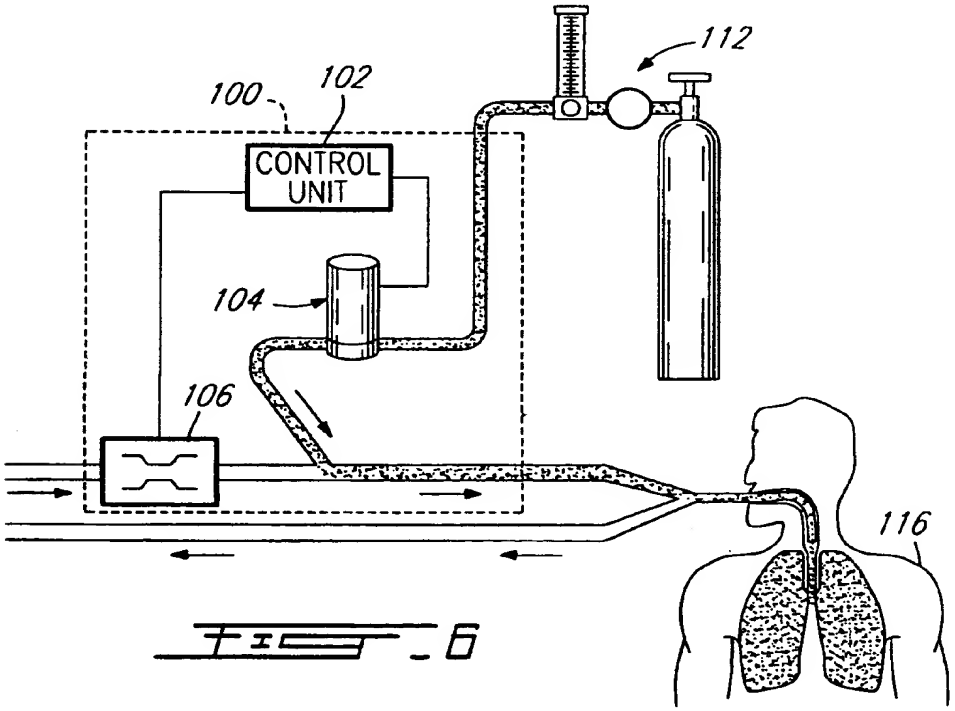
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Fig. 6

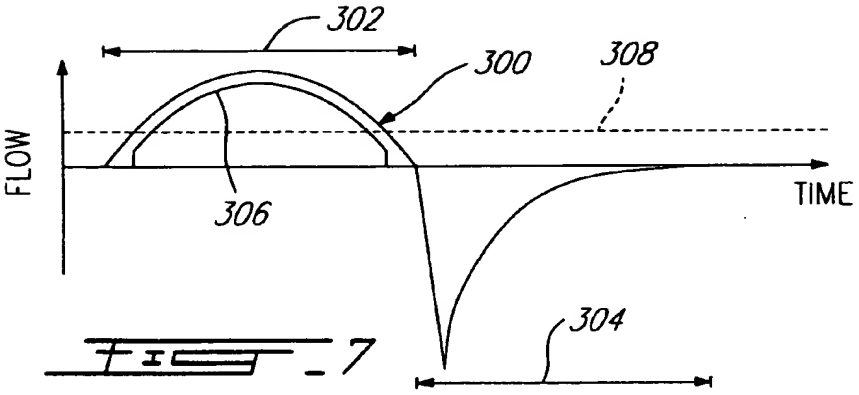


Fig. 7

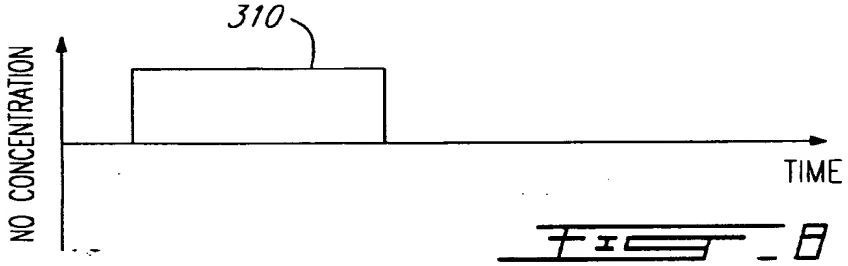


Fig. 8

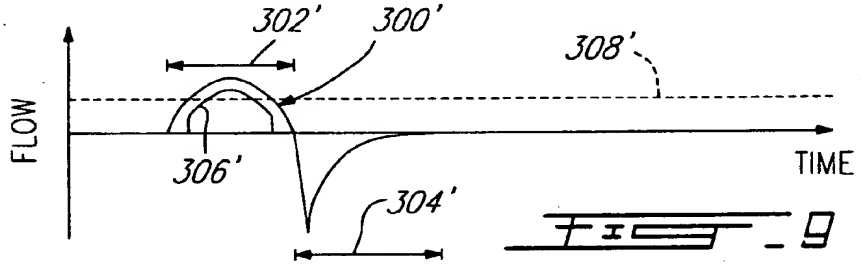


Fig. 9

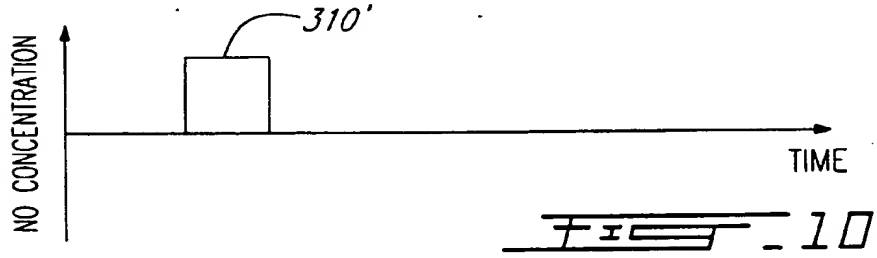


Fig. 10

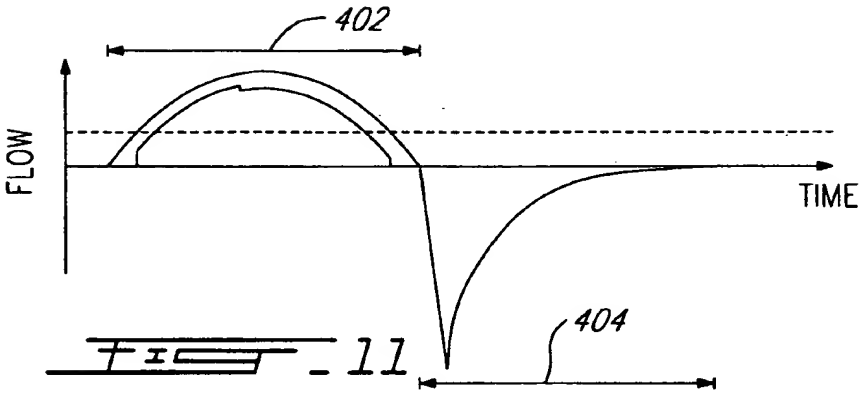


Fig - 11

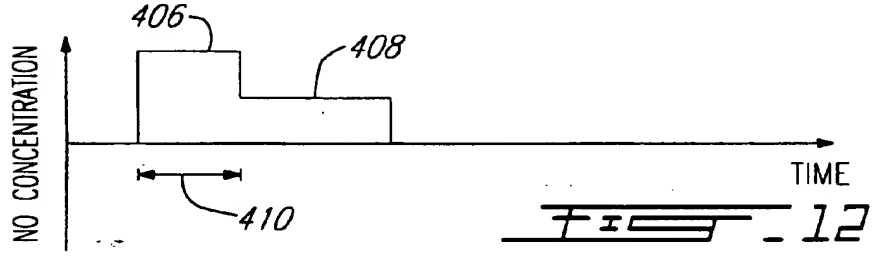


Fig - 12

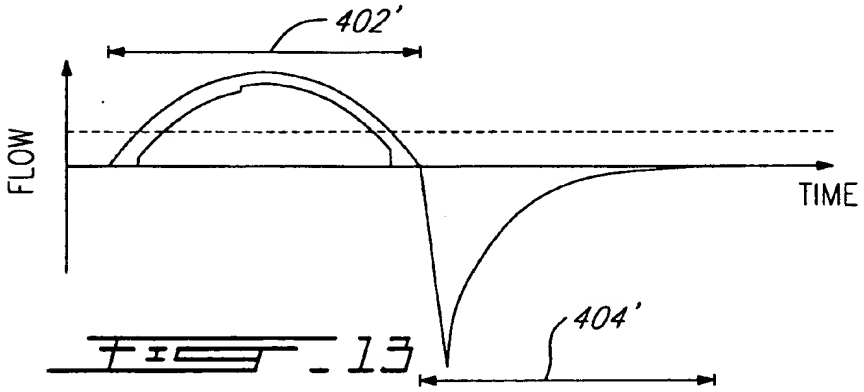


Fig - 13

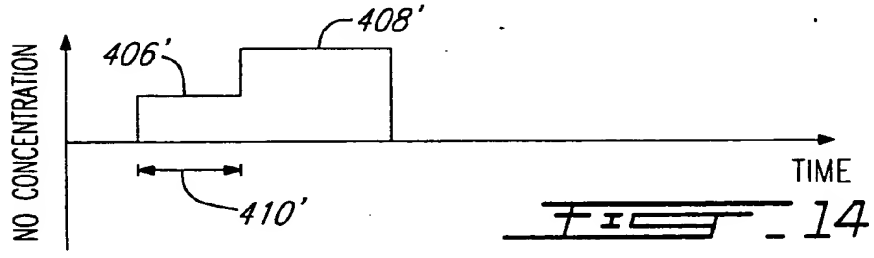
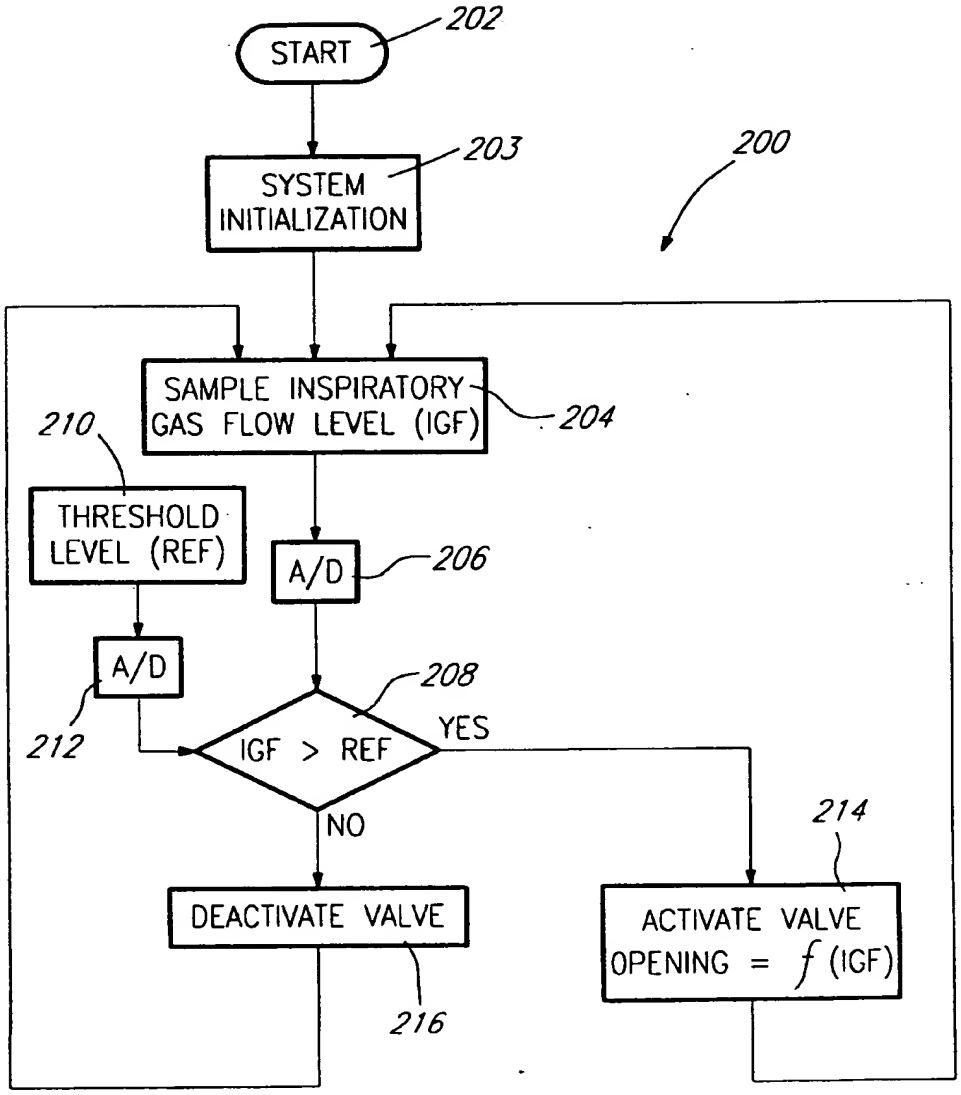


Fig - 14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A/D
212
208
IGF > REF
YES
NO
214
DEACTIVATE VALVE
216
ACTIVATE VALVE OPENING = f (IGF)

Fig. 15

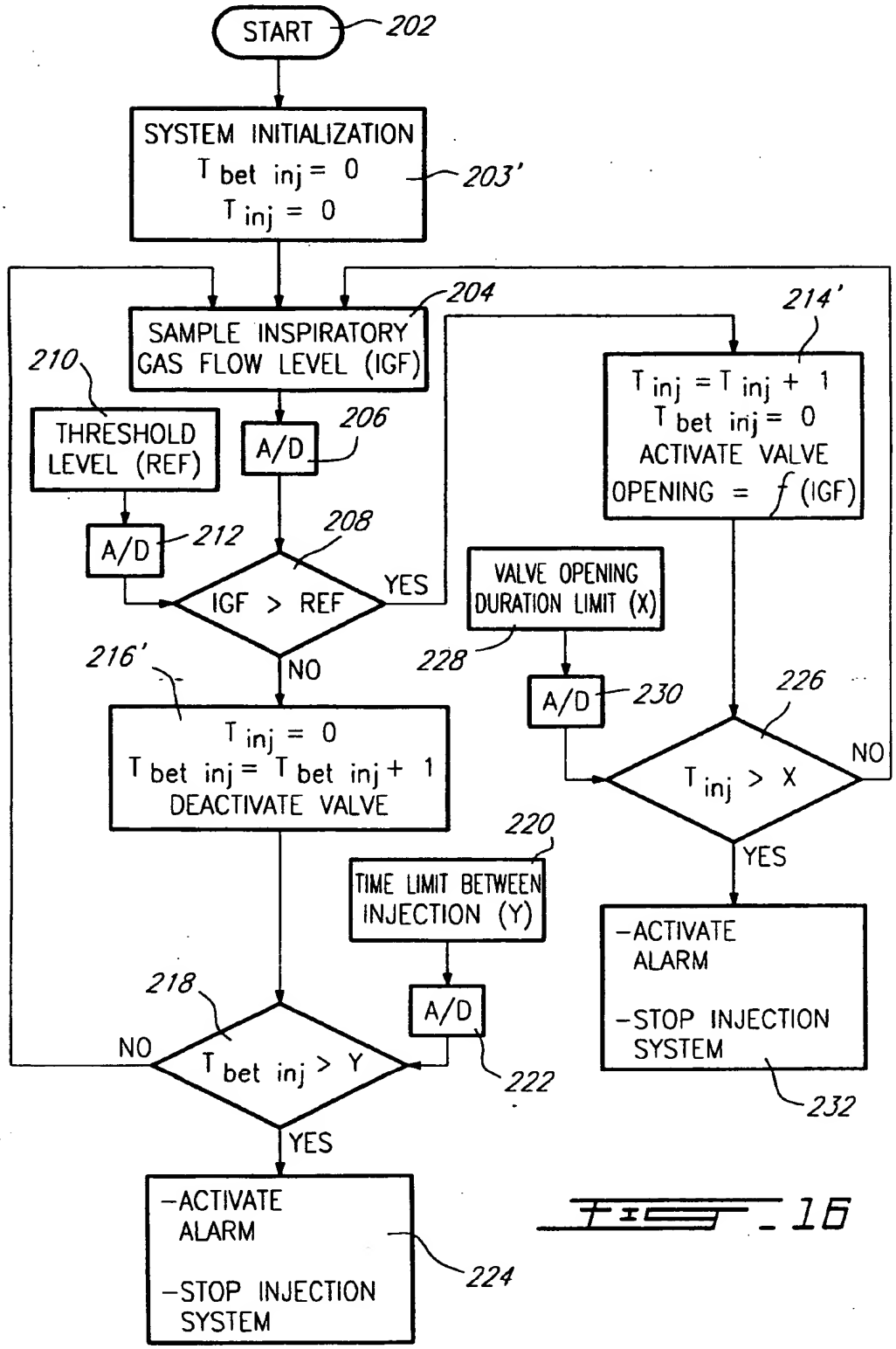
START
202
SYSTEM INITIALIZATION
T bet inj = 0
T inj = 0
203'
SAMPLE INSPIRATORY GAS FLOW LEVEL (IGF)
204
210
THRESHOLD LEVEL (REF)
A/D
206
A/D
212
208
IGF > REF
YES
NO
216'
T inj = 0
T bet inj = T bet inj + 1
DEACTIVATE VALVE
214'
T inj = T inj + 1
T bet inj = 0
ACTIVATE VALVE
OPENING = f (IGF)
VALVE OPENING DURATION LIMIT (X)
228
A/D
230
226
T inj > X
NO
YES
220
TIME LIMIT BETWEEN INJECTION (Y)
A/D
222
218
NO
T bet inj > Y
YES
-ACTIVATE ALARM
-STOP INJECTION SYSTEM
224
-ACTIVATE ALARM
-STOP INJECTION SYSTEM
232

Fig. 16